DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 20, 2015

Neometrics, Inc.
Mr. Gene Champeau
CEO
2605 Fernbrook Lane, Suite J
Plymouth, Minnesota 55447

Re: K143135
Trade/Device Name: Spring Coil Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 27, 2015
Received: January 28, 2015

Dear Mr. Champeau,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143135

Device Name
Spring Coil Guidewire

Indications for Use *(Describe)*
To facilitate the placement of devices during diagnostic or interventional procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter:	NeoMetrics, Inc. 2605 Fernbrook Lane North, Suite J Plymouth, MN 55447 763-559-4440 763-559-7676
Contact Person:	Eugene Champeau, CEO 2605 Fernbrook Lane North, Suite J Plymouth, MN 55447
Date Prepared:	January 27, 2015
Device Name:	Spring Coil Guidewire
Device Common Name:	Catheter Guide Wire
Classification:	Class II Regulation Number: 21 CFR 870.1330.
Product Code:	DQX
Predicate Device:	Company Name: Lake Region Medical. Brand Name: Cadiovascular Spring Guides 510(k) number: K770977
Device Description:	NeoMetrics guidewires are constructed using stainless steel and nickel titanium alloys. Configurations include a single tip or dual tip, retracted core or fixed core, and straight or J-tipped. The guidewire is packaged in a spiral hoop fitted with a "J"-Straightener, where applicable to aid in insertion of the guidewire into the puncture needle.
Indication for Use:	To facilitate the placement of devices during diagnostic or interventional procedures.
Principle of Operation:	The Spring Coil Guidewire is manually inserted into a vessel and advanced to the target region; it is a non-steerable guidewire.
Device Characteristics Compared to the Predicate:	The Spring Coil Guidewire has the same technological characteristics as the predicate guidewires.

Performance Data: To verify that device design met functional and performance requirements, representative samples of the device underwent bench testing in accordance to applicable standards and guidances.

Performance Testing:

- Dimensional Verification
- Tensile Strength
- Tip Flexibility
- Packaging Study
- Kink Resistance
- Fracture Resistance
- Flex Resistance
- Corrosion Resistance
- Biocompatibility Testing
- Radiopacity Testing

These data demonstrates that the Spring Coil Guidewire is equivalent to the predicate.

Conclusion: NeoMetrics Inc. considers the Spring Coil Guidewire to be equivalent to the predicate device. This conclusion is based upon the fact that device has an equivalent intended use, and there are no differences that raise new types of questions of safety and effectiveness.